

**REMARKS**

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.116, are respectfully requested in light of the remarks which follow.

**I. Substance of Interview Statement**

Applicants would like to thank the Examiner for the interview with Applicants' representative on May 14, 2009. Prior to the interview, the Examiner kindly agreed to review a proposed response provided by Applicant's representative. During the interview, the proposed response was discussed. In particular, the Examiner indicated that the proposed amendments to the claims should be sufficient to overcome all of the outstanding objections and rejections. The Examiner also suggested editorial amendments to new claim 118. Accordingly, Applicants amend the claims as set forth herein.

**II. Claim Amendments**

By the foregoing amendments to the claims, claims 102, 105, 106, 109, 111 and 113 have been amended; claims 103, 104, 107, 108, 110, and 112 have been canceled; and new claims 117-119 have been added.

In particular, the claims have been amended to clarify that the  $\alpha$ - and/or  $\beta$ -subunit variants are limited solely to the recited substitutions.

In addition, claim 102 has been further amended to recite that the  $\beta$ -subunit comprises SEQ ID NO: 2, and to incorporate the subject matter of claim 103.

Claim 106 has been rewritten in independent form and further amended to recite additional embodiments of the variant nitrile hydratase (i.e. particular combinations of the variant  $\alpha$ - and  $\beta$ -subunits) that were previously recited in claims 107 and 108.

Claim 109 has been further amended to recite that the  $\alpha$ -subunit comprises SEQ ID NO: 1, and to incorporate the subject matter of claim 110.

New claim 118 is directed to subject matter identified by the Examiner as enabled (see, e.g., page 6, paragraph 17, of the Office Action) and allowable (see, e.g., page 9, paragraph 27, of the Office Action).

Other amendments to the claims have also been made to clarify the claim language, for consistency, and to bring the claims into better conformance with U.S. patent practice.

These amendments are merely editorial in nature and are not intended to change the scope of the claims or any elements recited therein.

The amendments to the claims, including cancellation of claims, have been made without prejudice or disclaimer to any subject matter recited or canceled herein. Applicants reserve the right to file one or more continuation and/or divisional applications directed to any canceled subject matter. No new matter has been added, and entry of the foregoing amendments to the above-identified application are respectfully requested.

### **III. Response to Objections to the Claims**

At page 3 of the Office Action, the claims have been objected to for a number of reasons.

To expedite prosecution in the present application, and not to acquiesce to the Examiner's objections, the claims have been amended as set forth above. Applicants submit that the amendments clarify the claim language and should be sufficient to address the Examiner's concerns.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the objections.

### **IV. Response to Claim Rejections Under 35 U.S.C. § 112, Second Paragraph**

At pages 3-5 of the Office Action, claims 102-113 have been rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite for a number of reasons.

To expedite prosecution in the present application, and not to acquiesce to the Examiner's rejections, the claims have been amended in accordance with the Examiner's suggestions.

Applicants submit that the claims as amended particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the indefiniteness rejections.

### **V. Response to Claim Rejections Under 35 U.S.C. § 112, First Paragraph**

A. At pages 5-6 of the Office Action, claims 102-113 have been rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the written description requirement.

Specifically, the Examiner has stated that the claims encompass variants comprising essentially any structure.

**B.** At pages 6-7 of the Office Action, claims 102-113 have been rejected under 35 U.S.C. § 112, first paragraph, as purportedly lacking enablement.

The Examiner has acknowledged that the specification enables a nitrile hydratase variant comprising (a) a variant of SEQ ID NO: 1 which differs from SEQ ID NO: 1 solely by substitutions at positions 6, 19, 36, 71, 148, 204, 19, and/or 204, and (b) a variant of SEQ ID NO: 2 which differs from SEQ ID NO: 2 solely by substitutions at positions 10, 20, 21, 32, 37, 41, 46, 48, 51, 72, 108, 118, 127, 146, 160, 186, 200, 212, and 217. However, according to the Examiner the specification does not enable nitrile hydratase variants comprising any number of additional modifications to the polypeptides of SEQ ID NOS: 1 or 2.

To expedite prosecution in the present application, and not to acquiesce to the Examiner's rejection, the claims have been amended as set forth above, to clarify that the  $\alpha$ - and/or  $\beta$ -subunit variants are limited solely to the recited substitutions. Furthermore, claims 102 and 109 have been amended to recite that the  $\alpha$ - and  $\beta$ -subunits comprise SEQ ID NOS: 2 and 1, respectively.

Thus, the recited nitrile hydratase variants are adequately described and enabled, and Applicants respectfully request reconsideration and withdrawal of the written description and enablement rejections under 35 U.S.C. § 112, first paragraph.

## **VI. Response to Claim Rejections Under 35 U.S.C. § 102(b)**

At pages 8-9 of the Office Action, claim 109 has been rejected under 35 U.S.C. § 102(b) as purportedly being anticipated by Kobayashi et al. (*Biochimica et Biophysica Acta*, 1991).

It is well established that for prior art to be anticipatory, every element of the claimed invention must be disclosed in a single item of prior art in the form literally defined in the claim. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 213 U.S.P.Q. 81, 90 (Fed. Cir. 1986). Applicants submit that Kobayashi et al. fails to satisfy this requirement, for at least the following reasons.

As noted above, the claims have been amended to clarify that the  $\alpha$ - and/or  $\beta$ -subunit variants are limited solely to the recited substitutions. Applicants submit that Kobayashi et al. fails to teach or even suggest the  $\alpha$ - and/or  $\beta$ -subunit variants recited in the present claims.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

**CONCLUSION**

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Amendment and Reply or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney so that prosecution of this application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: May 15, 2009

By: Lisa E. Stahl R. K. Mullen  
Lisa E. Stahl  
Registration No. 56,704  
Reg. No. 28531

Customer No. 21839  
703 836 6620